

REMARKS

Applicant has canceled claim 103 without prejudice. Applicant has amended claims 75 and 93 to correct form and clerical errors. Claims 98 and 99 have been amended solely for greater clarity. The claim amendments are fully supported by the original specification. No new matter has been introduced and no new issue has been raised. The amendments are made solely to expedite prosecution of the application and Applicant reserves the right to pursue subject matter as originally claimed in the present or future applications.

Applicant notes that the previous amendments mailed on February 16, 2007 and May 22 were not entered. Applicant respectfully requests entry of these prior two amendments and the present claim amendment as filed herein.

Applicant respectfully requests entry of this amendment and reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action mailed December 19, 2006.

Priority

6. The Examiner maintains that claims 86, 87, 98, and 99 do not properly benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents cited, since these claims stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description and a sufficiently enabling disclosure. The Examiner has deemed the effective filing date of claims 86, 87, 98, and 99 as the filing date of the instant application: August 26, 2003. Applicant respectfully disagrees.

Applicant reiterates the arguments already made of record and submit that the parent applications (Serial Nos. 10/274,177 and 10/229,345) as filed are fully compliant with the requirements of the first paragraph of 35 U.S.C. § 112. Nevertheless, Applicant has amended claims 98 and 99 to clarify the subject matter which benefits from the filing dates of the earlier filed applications. With regard to claims 86 and 87, the parent applications both disclose using a biological sample such as a stool sample; U.S. Application No. 10/274,177 describes detecting

markers in stool samples (see, for example, paragraphs 0004, 0014, 0112, 0114, 0144, 0150, and claim 17), and U.S. Application No. 10/229,345 similarly describes using stool samples. Therefore, amended claim 87 is entitled to benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents.

Grounds of Objection and Rejection Maintained

8. The Examiner maintains the objection of claims 75, 84-91, 93, and 95-106 because the claims are directed in the alternative to the subject matter of a non-elected invention.

Applicant notes with appreciation that Applicants' Petition to withdraw the Restriction Requirement submitted on May 22, 2007 has been granted. As a result, claims 94 and 123 have been rejoined with the elected invention. Claims 75, 84-91, 93-102, 104-106, 123-125 are currently under examination.

Claim Rejections under 35 U.S.C. § 112

9. The Examiner maintains the rejection of claims 99, 100, and 103 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) With regard to claim 99, the Examiner contends that the metes and bounds of “the subject’s historical baseline” are not clear. In an effort to expedite prosecution, Applicant has amended claim 99 as suggested by the Examiner thus rendering this rejection moot.

(b) Claims 100 and 103 stand rejected as allegedly being indefinite. Claim 100 stands rejected because, according to the Examiner, it is not clear why the presence of the polypeptide indicates that the subject is likely to harbor a colon adenoma or a colon cancer as opposed to some other type of colon neoplasm. The Examiner suggests amending claim 100 to recite “wherein said colon neoplasm is a colon adenoma or a colon cancer”. The claim is hereby amended according to the Examiner’s suggestion in order to more clearly point out the claimed invention. This amendment does not change the scope of the claimed invention.

The Examiner has similarly rejected claim 103 and argues that it is not clear whether or not the outcome of claim 103 requires some other active step that is not recited. Applicant disagrees with the Examiner's position. Nevertheless, solely to expedite prosecution of the application, Applicant has canceled claim 103 without prejudice, rendering the rejection moot.

Applicant believes the claim amendments obviate the rejections and respectfully requests reconsideration and withdrawal of these rejections.

10. The Examiner maintains the rejection of claims 98 and 99 under 35 U.S.C. § 112, first paragraph, written description. The Examiner maintains that the claims are directed to particular values and that the values of a “predetermined standard” and a “subject’s historical baseline” are not sufficiently described. Although Applicant disagrees with the Examiner, Applicant has considered the Examiner’s suggested claim amendment on page 9 of the Office Action and has amended claims 98 and 99 accordingly. Claim 98 as amended recites active steps of determining amounts of polypeptides and comparing the amounts. Claim 99 has also been amended to obviate this ground of the rejection. The claims fully satisfy the written description requirement, as the claim terms and recited steps are fully described throughout the specification (see, e.g., lines 23-27 on page 3 and lines 13-17 on page 20). Accordingly, Applicant requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, written description.

11. The Examiner also maintains the rejection of claims 98 and 99 under 35 U.S.C. § 112, first paragraph, enablement for reasons of record. Applicant traverses. Nonetheless, and solely to expedite prosecution, Applicant has amended claims 98 and 99 as described above. In view of these claim amendments, Applicant believes the claimed invention is enabled and requests reconsideration and withdrawal of the rejection.

New Ground of Objection

12. The Examiner objects to claim 124 insofar as it is directed to the subject matter of the non-elected species of invention.

Applicant respectfully disagrees. Claim 124 is directed to SEQ ID NO: 3 which is the elected sequence. Clarification is respectfully requested.

Advisory Action Mailed March 20, 2007

The Advisory Action asserts that claim 125 is directed to an invention that is patentably distinct from the elected invention (i.e., the invention of Group I, claims 75-107). Solely to expedite prosecution of the application, Applicant has canceled claim 125 without prejudice; the subject matter has been included in amended claim 103.

The Advisory Action further asserts that claim 75 includes non-elected species by reciting "a secreted polypeptides produced by the expression of a nucleic acid having the sequence of SEQ ID NO: 5," but the only species described with any particularity is the polypeptide of SEQ ID NO: 3. The Examiner further asserts that entry of the amendment would raise new issues under 35 U.S.C. § 112, both in terms of the written description and enablement provisions set forth thereunder.

Applicant respectfully disagrees. Contrary to the Examiner's assertion, the specification teaches at least two species sequences, SEQ ID NO: 3 and SEQ ID NO: 21 (e.g., lines 13-21 on page 8, and Example 13 on page 57). Applicant further points out that the specification sufficiently teaches association of colon neoplasm with the presence of either SEQ ID NO: 3 or 21 and also provides working examples (e.g., Examples 1, 5, 6, 7, 10, 11, 12, and 13). Thus, all pending claims as amended satisfy both written description and enablement requirements.

Further, as described above, claims 94 and 123 have been rejoined with the elected invention as a result of the grant of Applicant's Petition to withdraw the Restriction Requirement.

Advisory Action Mailed July 10, 2007

The Advisory Action asserts that entry of proposed amendment would raise new issues that would require further consideration and/or search, raise the issue of new matter "because, for example, the amendment would change claim 75 to read, 'by the expression of the nucleic acid having the amino acid sequence of SEQ ID No: 5', where SEQ ID NO: 5 identifies a nucleotide sequence, not an amino acid sequence."

Applicant respectfully disagrees. One of skill in the art would readily know that SEQ ID NO: 5 is a nucleotide sequence, although SEQ ID NO: 5 is incorrectly referred to as the "amino acid

sequence." Nonetheless, Applicant has amended claims 75 and 93 to correct form and clerical errors. Applicant has also amended claims 98-99 solely for greater clarity. Withdrawal and reconsideration of the rejections are respectfully requested.

CONCLUSION

In view of the amendments and at least the forgoing remarks, Applicant believes the pending claims are in condition for allowance. If any additional fees are due, please charge our Deposit Account No. 18-1945, under Order No. **CWRU-P03-003** from which the undersigned is authorized to draw.

Dated: August 21, 2007

Respectfully submitted,

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